

REMARKS

This submission is in response to the Restriction Requirement dated December 11, 2002. Claims 8 and 30 have been amended. Claims 1-46 are pending. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

Claims 8 and 30 have been amended to be in independent form. Specifically, these claims were amended to recite the limitations of the nonelected claims from which they depended prior to this amendment. Support for these amendments can be found throughout the specification and in the originally filed claims (specifically, original claim 1 for amended claim 8 and original claim 26 for amended claim 30). Thus, no new matter has been added by way of this amendment.

THE RESTRICTION REQUIREMENT

The Examiner has required a restriction of the pending claims to one of the following groups:

I. Claims 1-7, 40 and 41, drawn to a lysyl oxidase polypeptide (EER-7) or a fragment thereof;

II. Claims 8-14 (*claim 15 should also be included*) and 17-20, drawn to nucleic

acids encoding EER-7, host cells comprising a vector encoding EER-7 and a method of making EER-7 using host cells in culture;

III. Claim 15 sic, (*claim 16, not claim 15, is directed to an animal transformed with a vector, and this group should include claim 16, not claim 15*) drawn to an animal transformed with a vector encoding EER-7;

IV. Claims 21 and 22, drawn to an antibody that recognizes EER-7 and a method of detecting EER-7 using said antibody;

V. Claims 23-25, drawn to a method of detecting EER-7 expression by detecting mRNA encoding EER-7;

VI. Claims 26-29 and 42-44, drawn to cells transfected with DNA encoding different estrogen receptors;

VII. Claims 30-39, drawn to a method of identifying compounds using cells transfected with DNA encoding different estrogen receptors and detecting EER-7 expression by detecting mRNA encoding EER-7;

VIII. Claim 45, drawn to a knockout, non-human animal in which EER-7 expression is suppressed; and

IX. Claim 46, drawn to a non-human animal comprising a vector encoding a protein that regulates EER-7

In order to be fully responsive to the Requirement for Restriction,

Applicants hereby provisionally elect, with traverse, to prosecute claims 8-15 and 17-20, corresponding to Group II. Applicants respectfully point out that claim 15 should be included with Group II. Claim 15 is not directed to an animal transformed with a vector, as indicated as the subject matter of Group III, but is directed to a host cell comprising a vector encoding EER-7. As indicated in the Examiner's Group II, claims directed to host cells comprising a vector encoding EER-7 are a part of Group II. Thus, claim 15 should be considered with the claims of Group II and is herein elected along with claims 1-14 and 17-20.

Applicants respectfully traverse the Requirement for Restriction and reserve the right to petition therefrom under 37 C.F.R. § 1.144. Applicants respectfully request reconsideration of the Restriction Requirement. In particular, Applicants respectfully request reconsideration of the Restriction Requirement to allow prosecution of Groups V and VII with elected Group II.

Applicants believe that Groups II, V and VII should be examined together pursuant to 35 U.S.C. §103(b)(2), under which a patent issued on a biotechnological process shall also contain claims directed towards the composition of matter utilized by that process. 35 U.S.C. §103(b) mandates that "a biotechnological process (in the present case, detecting EER-7 expression) using or resulting in a composition of matter that is novel under Section 102 and nonobvious under Section 103(a) shall be considered non-obvious if claims to the process and the composition of matter are

contained in the same application for patent ..." 35 U.S.C. § 103(b)(1)(A). Using the novel products of Group II in any process requires determining the novelty of the products of Group II. Once the novelty of these products is established, methods of using these products are patentable. *In re Ochiai*, 37 USPQ 2d. 1127 (Fed. Cir. 1995). Thus even if the process of using the nucleic acids represents patentably distinct subject matter, this subject matter should nevertheless be considered with the product claims.

Under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." See, M.P.E.P. § 803 (emphasis added). The groups of claims designated by the Examiner (*i.e.*, Groups II, V and VII, *supra*) do not, however, define products and methods for using such products with biological properties which are distinct or which warrant separate examination and searches. Rather, the claims represent a web of knowledge and continuity of effort that merits examination in a single application. The conjoint examination and inclusion of all of the claims of groups II, V and VII in the instant application is therefore appropriate and would not present an undue burden on the Examiner.

Further, pursuant to 37 C.F.R. § 1.141(b), "the process of using [a claimed product] may be joined with the claims directed to the product and the process

of making the product even though a showing of distinctiveness between the product and the process of using the product can be made."

Applicant respectfully submits that Groups II, V and VII designated by the Examiner fail to define products and methods for using such products that warrant separate examination and search. A thorough search of the subject matter of claims 8-15 and 17-20 of Group II would necessarily include a search of the subject matter of Groups V and VII as they all involve EER-7 nucleotide sequences. Furthermore, Groups V and VII fall into the same class and subclass, demonstrating that the subject matter of these claims would be searched together. The Examiner contends that the process defined by the claims of Group V (claims 23-25) can be performed using an antibody. Applicants respectfully disagree. Claim 22 and its dependent claims 24 and 25 recite "detecting mRNA." It is well known in the art that detecting mRNA involves the use of oligonucleotides. Similarly, the methods recited in the claims of Group VII require detection of mRNA, and thus require the use of the nucleic acids recited in the claims of Group I.

Hence, it is believed that a single search of the features of the product recited the claims of Group II would necessarily and inescapably require a search of the subject matter of Groups V and VII. Accordingly, Applicants respectfully request that the Examiner withdraw the Requirement for Restriction.

CONCLUSION

Therefore, in view of the above amendments and remarks, it is respectfully requested that the restriction requirement be reconsidered.

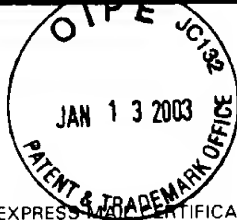
If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mark J. EVANS ; Marshall SCICCHITANO; Ashok BAPAT; Eric BEER; Ramesh A. BHAT; Elissa FERRIS

Serial No.: 09/924,946

Art Unit: 1642

Confirmation No.: 3104

Filed: August 8, 2001

Examiner: Michael C. Wilson

For: A NOVEL MEMBER OF THE LYSYL OXIDASE GENE FAMILY

MARK-UP CLAIMS FOR AMENDMENT PURSUANT TO 37 C.F.R. § 1.121

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

January 13, 2003

Sir:

8. (Amended) An isolated nucleic acid encoding [the] an EER-7 protein [of claim 1] having an amino acid sequence comprising at least 10 contiguous amino acids

from the sequence depicted in SEQ ID NO:2 or which has at least 60% sequence similarity with SEQ ID NO:2, which EER-7 protein has (i) lysyl oxidase activity; (ii) comprises four copies of a SRCR domain having a sequence greater than 80% similar to a sequence selected from the group consisting of SEQ ID NOs: 3, 4, 5, and 6; and (iii) comprises a conserved catalytic domain of lysyl oxidase enzymes having a sequence as depicted in SEQ ID NO: 7.

30. (Amended) A method for identifying a compound that selectively regulates *EER-7* mRNA transcription through an estrogen receptor, which method comprises detecting a difference in the level of *EER-7* mRNA in an assay system [of claim 26] comprising transformed cells that express different functional estrogen receptors, wherein the number of cells is sufficient to transcribe a detectable amount of mRNA encoding EER-7 contacted with a test compound, wherein a difference in the level of *EER-7* mRNA indicates that the test compound selectively regulates the estrogen receptor.